68-13-2. Definitions. As used in this article of the board's regulations, each of the following terms shall have the meaning specified in this regulation:

(a) "Active ingredients" means chemicals, substances, or other components intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans or for use as nutritional supplements.

(b) "Added substances" and "inactive ingredients" mean the ingredients necessary to compound a sterile preparation or nonsterile preparation and not intended or expected to cause a human pharmacologic response if administered alone in the amount or concentration contained in a single dose of the drug product.

(c) "Antearea" means an area, separate from the buffer area, that meets the requirements of an ISO class eight environment and in which personal hygiene and garbing procedures, staging of components, order entry, and labeling are performed.

(d) "Batch" means multiple sterile dosage units in a quantity greater than 25 that are compounded in a discrete process by the same individual or individuals during one limited period.

(e) "Beyond-use date" means a date placed on a prescription label at the time of dispensing, repackaging, or prepackaging that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(f) "Biological safety cabinet" and "BSC" mean a ventilated cabinet for sterile preparations and hazardous drugs to protect personnel, products, and the environment that has an open front with inward airflow for protection of personnel, downward-airflow LAFS for product protection, and HEPA-filtered exhausted air for environmental protection.

(g) "Buffer area" means an area that meets the requirements for an ISO class seven environment and in which the primary engineering control is located.

(h) "Clean room" means a room that meets the requirements for an ISO class five environment.

(i) "Complex nonsterile compounding" means making a nonsterile preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Nonsterile preparations made using complex nonsterile compounding shall include transdermal dosage forms, modified-release forms, and suppositories for systemic effects.

(j) "Component" means any active ingredient or added substance intended for use in the compounding of a drug product, including any ingredient that does not appear in the drug product.

(k) "Compounding" has the meaning specified in K.S.A. 2017 Supp. 65-1626, and amendments thereto.

(l) "Compounding area" means any area in a pharmacy or outsourcing facility where compounding is performed.

(m) "Compounding aseptic containment isolator" and "CACI" mean a compounding aseptic isolator designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer process and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment shall not occur unless the air is first passed through a HEPA filter capable of containing airborne concentrations of the physical size and state of the drug being compounded.

Whenever volatile hazardous drugs are compounded, the exhaust air from the CACI shall be removed by the building's ventilation system.

(n) "Compounding aseptic isolator" and "CAI" mean a type of isolator specifically designed for compounding sterile preparations or nonsterile preparations and designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the CAI from the surrounding environment shall not occur unless the air has first passed through a HEPA filter and an ISO class five environment is maintained.

(o) "Cytotoxic," when used to describe a pharmaceutical, means that the pharmaceutical is capable of killing living cells. This term is also used to describe components classified as cancer chemotherapeutic, carcinogenic, mutagenic, or antineoplastic.

(p) "Dosage unit" means the amount of a sterile preparation that would be administered to or taken by one patient at a time.

(q) "Endotoxin" means a potentially toxic, natural compound that is a structural component of bacterial cell walls and that is released mainly when bacteria undergo destruction or decomposition.

(r) "Essentially a copy" means any sterile preparation or nonsterile preparation that is comparable in active ingredients to a commercially available drug product, unless either of the following conditions is met:

(1) There is a change made for an identified individual patient that produces a clinically significant difference for the patient, as determined by the prescribing practitioner, between the comparable commercially available drug product and either the sterile preparation or the

nonsterile preparation.

(2) The drug appears on the drug shortage list in section 506E of the federal food, drug, and cosmetic act, 21 U.S.C. 356e, at the time of compounding, distribution, and dispensing.

(s) "Excursion" means a deviation from the range of temperatures specified by the manufacturer for storage or transport of a pharmaceutical based on stability data.

(t) "Glove fingertip test" means a test in which a gloved fingertip is pressed to and cultured on a microbiological growth media plate. Each successful glove fingertip test shall yield no more than three colony-forming units per contact plate for the annual competency evaluation and shall yield zero colony-forming units at least three times for the initial competency evaluation.

(u) "Hazardous drug" means any drug or compounded drug identified by at least one of the following criteria:

(1) Carcinogenicity;

(2) teratogenicity or developmental toxicity;

(3) reproductive toxicity;

(4) organ toxicity at low doses;

(5) genotoxicity; or

(6) drug product structure or toxicity that mimics that of existing hazardous drugs.

(v) "HEPA" means high-efficiency particulate air.

(w) "ISO class eight environment" means an atmospheric environment containing less than 3,520,000 airborne particles measuring at least 0.5 micron in diameter per cubic meter of air.

(x) "ISO class five environment" means an atmospheric environment containing less than

3,520 airborne particles measuring at least 0.5 micron in diameter per cubic meter of air.

(y) "ISO class seven environment" means an atmospheric environment containing less than 352,000 airborne particles measuring at least 0.5 micron in diameter per cubic meter of air.

(z) "Laminar airflow system" and "LAFS" mean an apparatus designed to provide an ISO class five environment for the compounding of sterile preparations using air circulation in a defined direction that passes through a HEPA filter.

(aa) "Manufacturing" means manufacture as defined in K.S.A. 65-1626, and amendments thereto.

(bb) "Media fill test" means a test in which a microbiological growth medium, which may consist of a soybean-casein digest medium, is substituted for an actual drug product to simulate admixture compounding. The media fill test shall be successful if it produces a sterile preparation without microbial contamination.

(cc) "Moderate nonsterile compounding" means making a nonsterile preparation that requires special calculations or procedures to determine quantities of components per nonsterile preparation or per dosage unit or making a nonsterile preparation for which stability data is not available. Nonsterile preparations made using moderate nonsterile compounding shall include morphine sulfate suppositories, diphenhydramine troches, and a mixture of two or more manufactured creams if stability of the mixture is not known.

(dd) "Multiple-dose container" means a multiple-unit container for any sterile preparation intended only for parenteral administration, usually containing antimicrobial preservatives.

(ee) "Nonsterile preparation" means a pharmaceutical made using simple nonsterile compounding, moderate nonsterile compounding, or complex nonsterile compounding.

(ff) "Official compendium" has the meaning specified in K.S.A. 65-656, and amendments thereto.

(gg) "Order" means either a prescription order as defined in K.S.A. 65-1626, and amendments thereto, or a medication order as defined in K.A.R. 68-5-1.

(hh) "Parenteral," when used to refer to a solution, means that the solution is administered by injection through one or more layers of skin or by other routes of administration that bypass the gastrointestinal tract.

(ii) "Parenteral product" means a sterile preparation administered by injection through one or more layers of skin or by other routes of administration that bypass the gastrointestinal tract.

(jj) "Practitioner-patient-pharmacist relationship" means a relationship that meets all of the following conditions:

(1) The practitioner has assumed the responsibility for making medical judgments regarding the health of the patient and the need for medical treatment.

(2) The practitioner has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition, and the practitioner has examined the patient and is available for follow-up.

(3) The practitioner has communicated the necessary prescriptions to the pharmacist, who is able to provide pharmaceutical care to the patient and, if needed, communicate with the practitioner.

(kk) "Primary engineering control" means a clean room or an apparatus for compounding sterile preparations, including an LAFS, a BSC, a CAI, or a CACI, designed to provide an ISO

class five environment for compounding sterile preparations.

(ll) "Purified water" means water that meets the requirements for ionic and organic chemistry purity and protection from microbial contamination specified in section 1231 of the official compendium.

(mm) "Refrigeration" and "controlled cold temperature" mean a temperature maintained thermostatically between 2° and 8°C (36° to 46°F) that allows for excursions between 0° and 15°C (32° to 59°F) that are experienced during storage, shipping, and distribution, such that the allowable calculated mean kinetic temperature is not more than 8°C (46°F).

(nn) "Room temperature" means a temperature maintained thermostatically that meets the following criteria:

(1) Encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F);

(2) results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and

(3) allows for excursions between 15° and 30°C (59° to 86°F) experienced in pharmacies, hospitals, and storage facilities, such that the allowable calculated mean kinetic temperature remains in the allowed range.

(oo) "Segregated compounding area" means a designated, demarcated area or room that is restricted to compounding low-risk sterile preparations, which shall contain a primary engineering control providing unidirectional airflow that maintains an ISO class five environment and shall be void of all activities and materials extraneous to the sterile compounding process.

(pp) "Simple nonsterile compounding" means either of the following:

(1) Making a nonsterile preparation that has a compounding monograph listed in the official compendium or that appears in a peer-reviewed journal containing specifics on component quantities, compounding procedure, equipment, and stability data for the formulation and appropriate beyond-use dates; or

(2) reconstituting or manipulating commercially available products that require the addition of one or more ingredients as directed by the manufacturer.

Nonsterile preparations made using simple nonsterile compounding shall include captopril oral solution, indomethacin topical gel, and potassium bromide oral solution.

(qq) "Single-dose container" means a single-unit container for any sterile preparation intended for parenteral administration that is accessed once for one patient.

(rr) "Specific medical need" means a medical reason why a commercially available drug product cannot be used, excluding cost and convenience.

(ss) "Sterile preparation" means any dosage form of a drug, including parenteral products free of viable microorganisms, made using currently accepted aseptic compounding techniques under acceptable compounding conditions. This term shall include any commercially compounded sterile drug dosage form that has been altered in the compounding process.

(tt) "Sufficient documentation" means either of the following:

(1) A prescription documenting a specific medical need; or

(2) a notation in a pharmacy's or an outsourcing facility's records that verbal or other documentation of the specific medical need was received for each prescription, including the name of the person verifying the specific medical need, the date, and the specific medical need. (Authorized by K.S.A. 65-1630 and K.S.A. 2017 Supp. 65-1637e; implementing K.S.A. 2017

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68-13-3. Nonsterile preparations. (a) This regulation shall apply to the following:

(1) Nonsterile preparations that are compounded in Kansas; and

(2) nonsterile preparations that are shipped or delivered into Kansas by a pharmacy and are to be administered to a patient in Kansas.

(b) "Pharmacy," as used in this regulation, shall mean a pharmacy, nonresident pharmacy, or outsourcing facility as defined by K.S.A. 2017 Supp. 65-1626, and amendments thereto.

(c) Any pharmacist may compound a nonsterile preparation that is commercially available only if it is different from a product approved by the FDA and there is sufficient documentation of a specific medical need for an individual patient.

(d) A pharmacist shall not compound a nonsterile preparation by any of the following methods:

(1) Using any component withdrawn from the market by the FDA for safety reasons;

(2) receiving, storing, or using any drug component that is not guaranteed or otherwise determined to meet the requirements of an official compendium;

(3) compounding finished drugs from bulk active ingredients that do not meet the requirements of a monograph listed in the official compendium; or

(4) compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs.

(e) For the convenience of any patient, any pharmacist may compound a nonsterile preparation before receiving an order based on routine, regularly observed prescribing patterns.

(f) Compounding for non-human animals shall meet the same requirements as those for

human prescriptions, except that a pharmacist shall not compound bulk chemicals for food-producing animals.

(g) Each nonsterile preparation sold by a pharmacy to a practitioner for administration to a patient shall be packaged with a label that includes the following text: "For Office Use Only -- Not for Resale."

(h) Any pharmacy may distribute nonsterile preparations without a prescription, including providing limited quantities to a practitioner in the course of professional practice to administer limited quantities to an individual patient, if the nonsterile preparations are not intended for resale.

(i) Each pharmacy selling any prescription nonsterile preparation to a practitioner for office use shall maintain an invoice documenting the following:

(1) The name and address of the practitioner;

(2) the drug compounded, including the lot number and expiration date of each component;

(3) the quantity sold; and

(4) the date of the transaction.

The invoice shall be maintained in the pharmacy and shall be made readily available to the pharmacist-in-charge, the board, and the board's designee.

(j) Within each pharmacy in which compounding occurs, one area shall be designated as the principal compounding area, where all nonsterile compounding shall take place.

(1) Each compounding area shall be well-lighted and well-ventilated, with clean and sanitary surroundings, and shall be free of food and beverages.

(2) Each compounding area shall provide the drugs, chemicals, and devices with necessary protection from deterioration due to light, heat, and evaporation and shall be arranged to protect all prescription drugs and devices from theft and any other unauthorized removal.

(3) All components used in compounding nonsterile preparations shall be stored in labeled containers in a clean, dry area and, if required, under proper refrigeration.

(4) Each compounding area shall include a sink that is equipped with hot and cold running water for hand and equipment washing.

(k) Each pharmacist compounding nonsterile preparations shall use purified water if the formulations indicate the inclusion of water.

(l) Each pharmacist-in-charge shall maintain a uniform formulation record for each nonsterile preparation, documenting the following:

(1) The ingredients, quantities, strength, and dosage form of the nonsterile preparation;

(2) the equipment used to compound the nonsterile preparation and the mixing instructions;

(3) the container used in dispensing;

(4) the storage requirements;

(5) the beyond-use date to be assigned;

(6) quality control procedures, which shall include identification of each person performing or either directly supervising or checking each step in the compounding process and which may include monitoring the following:

(A) Capsule weight variation;

(B) adequacy of mixing to ensure uniformity and homogeneity; and

(C) the clarity, completeness, or pH of solutions;

(7) the source of the formulation, including the name of the person, entity, or publication; and

(8) the name or initials of the person creating the formulation record and the date on which the formulation record was established at the pharmacy.

(m) Each pharmacist-in-charge shall maintain on the original order or on a separate, uniform record a compounding record for each nonsterile preparation, documenting the following:

(1) The name and strength of the nonsterile preparation;

(2) the identifier used to distinguish the nonsterile preparation's formulation record from other formulation records;

(3) the name of the manufacturer or repackager and, if applicable, the lot number and expiration date of each component;

(4) the total number of dosage units or total quantity compounded;

(5) the name of each person who compounded the nonsterile preparation;

(6) the name of the pharmacist, or the pharmacy student or intern working under the direct supervision and control of the pharmacist, who verified the accuracy of the nonsterile preparation;

(7) the date of compounding;

(8) the assigned internal identification number, if used;

(9) the prescription number, if assigned;

(10) the results of quality control procedures; and

(11) the assigned beyond-use date. In the absence of valid scientific stability information that is applicable to a specific drug or nonsterile preparation, the beyond-use date shall not be later than the expiration date of any component of the formulation and shall be established in accordance with the following criteria:

(A) For nonaqueous and solid formulations, either of the following:

(i) If a manufactured drug product is the source of the active ingredient, six months from the date of compounding or the time remaining until the manufactured drug product's expiration date, whichever is earlier; or

(ii) if a substance listed in an official compendium is the source of an active ingredient, six months from the date of compounding or the time remaining until the expiration date of any component of the formulation, whichever is earlier;

(B) for water-containing oral formulations, not more than 14 days when stored under refrigeration; and

(C) for water-containing non-oral formulations, not longer than the intended duration of therapy or 30 days, whichever is earlier.

(n) The compounding record and the corresponding formulation record specified in subsections (m) and (l), respectively, shall be retained at the pharmacy for at least five years and shall be made readily available to the pharmacist-in-charge, the board, and the board's designee.

(o) If a patient requests a transfer of the patient's prescription, a copy of the original prescription shall be transmitted upon the request of the receiving pharmacist. The transferring pharmacist shall also transfer the following written information with the prescription:

(1) Active ingredients;

(2) concentration;

(3) dosage form;

(4) route of delivery;

(5) delivery mechanism;

(6) dosing duration; and

(7) details about the compounding procedure.

(p) The pharmacist-in-charge shall ensure that all support personnel are trained and successfully demonstrate the following before performing delegated compounding:

(1) Comprehensive knowledge of the pharmacy's standard operating procedures with regard to compounding as specified in the policy and procedure manual; and

(2) familiarity with the compounding techniques used at the pharmacy. (Authorized by K.S.A. 65-1630 and K.S.A. 2017 Supp. 65-1637e; implementing K.S.A. 2017 Supp. 65-1626a, K.S.A. 65-1634, K.S.A. 65-1637c, and K.S.A. 2017 Supp. 65-1642; effective P-_____ _____.)

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68-13-4. Sterile preparations. (a) This regulation shall apply to the following:

(1) Sterile preparations that are compounded in Kansas; and

(2) sterile preparations that are shipped or delivered into Kansas by a pharmacy to be administered to a patient in Kansas.

(b) As used in this regulation, each of the following terms shall have the meaning specified in this subsection:

(1)(A) "High-risk," when used to describe a sterile preparation, means that the sterile preparation meets at least one of the following conditions:

(i) The sterile preparation is compounded from nonsterile ingredients or with nonsterile containers or equipment before terminal sterilization.

(ii) The sterile ingredients or components of the sterile preparation are exposed to air quality inferior to that of an ISO class five environment for more than one hour.

(iii) The sterile preparation contains nonsterile water and is stored for more than six hours before being sterilized.

(iv) The compounding pharmacist cannot verify from documentation received from the supplier or by direct examination that the chemical purity and content strength of the ingredients meet the specifications of an official compendium.

(v) The sterile preparation has been stored at room temperature and administered more than 24 hours after compounding, stored under refrigeration more than three days, or stored frozen from 0° to -20°C (32° to -4°F) or colder for 45 or fewer days, and sterility has not been confirmed by testing.

(B) This term shall apply to sterile preparations including the following:

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(i) Alum bladder irrigation solution;

(ii) any morphine preparation made for parenteral administration from nonsterile powder or tablets;

(iii) any total parenteral nutrition solution made from dried amino acids;

(iv) any total parenteral nutrition solution sterilized by final filtration; and

(v) any autoclaved intravenous solution.

(2) "Immediate use" means a situation in which a sterile preparation is compounded pursuant to an order in a medical care facility for administration to the patient within one hour of the start of compounding the sterile preparation.

(3) "Low-risk," when used to describe a sterile preparation, means that the sterile preparation meets the following conditions:

(A) In the absence of sterility testing, is stored at room temperature and administration to the patient has begun not more than 48 hours after compounding, is stored under refrigeration for 14 or fewer days before administration to the patient over a period not to exceed 24 hours, or is stored frozen at -20°C (-4°F) or colder for 45 or fewer days before administration to the patient over a period not to exceed 24 hours;

(B) is prepared for administration to one patient or is batch-prepared and contains suitable preservatives for administration to more than one patient; and

(C) is prepared by a simple or closed-system aseptic transfer of no more than three sterile, nonpyrogenic, finished pharmaceuticals obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers with no more than two instances in which a

transfer device passes through the designated access point into any one sterile container or package.

(4)(A) "Medium-risk," when used to describe a sterile preparation, means that the sterile preparation meets at least one of the following conditions:

(i) In the absence of sterility testing, is stored at room temperature and administered to the patient not more than 30 hours after compounding, is stored under refrigeration for nine or fewer days, or is stored frozen at -20°C (-4°F) or colder for 45 or fewer days;

(ii) is batch-prepared and intended for use by more than one patient or by one patient on multiple occasions;

(iii) is created by a compounding process that includes complex aseptic manipulations other than a single-volume transfer; or

(iv) is compounded by at least four manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container obtained from a licensed manufacturer by using a simple or closed-system aseptic transfer.

(B) This term shall apply to the following:

(i) Sterile preparations for use in a portable pump or reservoir over multiple days;

(ii) batch-reconstituted sterile preparations;

(iii) batch-prefilled syringes; and

(iv) total parenteral nutrient solutions that are compounded by the gravity transfer of carbohydrates and amino acids into an empty container with the addition of sterile additives using a syringe and needle or that are mixed with an automatic compounding device.

(5) "Pharmacy" means a pharmacy, nonresident pharmacy, or outsourcing facility as defined by K.S.A. 2017 Supp. 65-1626, and amendments thereto.

(c) Any sterile preparation for immediate use may be compounded outside a primary engineering control if both of the following conditions are met:

(1) Administration to the patient begins within one hour of the start of compounding the sterile preparation.

(2) The sterile preparation is compounded by a simple or closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers.

(d) When a multiple-dose container with antimicrobial preservatives has been opened or entered, the container shall be labeled with a beyond-use date not to exceed 28 days, unless otherwise specified by the manufacturer.

(e) Each compounding area shall contain a primary engineering control providing unidirectional airflow that will maintain an ISO class five environment for compounding sterile preparations and shall be void of all activities and materials that are extraneous to compounding.

(f) Each sterile preparation compounded in a segregated compounding area shall be labeled with a beyond-use date of no more than 12 hours.

(g) Each single-dose container shall be labeled as such.

(h) The contents of each single-dose container shall be used within one hour if the container is opened or entered in an area with air quality that does not meet the requirements of an ISO class five environment.

(i) The contents of each single-dose container shall be used within six hours if the container is opened or entered in an area that meets the requirements of an ISO class five environment.

(j) For the convenience of any patient, any pharmacist may compound a sterile preparation before receiving an order if the pharmacist has previously filled orders for the sterile preparation and the sterile preparation is based on routine, regularly observed prescribing patterns.

(k) Compounding for non-human animals shall meet the same requirements as those for human prescriptions, except that a pharmacist shall not compound bulk chemicals for food-producing animals.

(l) Each sterile preparation sold by a pharmacy to a practitioner for administration to a patient shall be packaged with a label that includes the following text: "For Office Use Only – Not For Resale."

(m) Any pharmacy may distribute sterile preparations without a prescription, including providing limited quantities to a practitioner in the course of professional practice to administer limited quantities to an individual patient, if the sterile preparations are not intended for resale.

(n) A pharmacist shall not compound a sterile preparation that is essentially a copy.

(o) Any pharmacist may compound a sterile preparation that is commercially available only if there is sufficient documentation of a specific medical need for the prescription or the product is temporarily unavailable due to problems other than safety or effectiveness. Each pharmacist shall document any unavailability in the patient's prescription record, including the

date the product was unavailable, and shall maintain documentation from the manufacturer or distributor demonstrating the product's unavailability. The pharmacist shall cease compounding the sterile preparation as soon as the product becomes commercially available.

(p) A pharmacist shall not compound a sterile preparation by any of the following methods:

(1) Using any component withdrawn from the market by the FDA for safety reasons;

(2) receiving, storing, or using any drug component that is not guaranteed or otherwise determined to meet the requirements of an official compendium; or

(3) compounding finished drugs through manufacturing, as defined in K.S.A. 65-1626 and amendments thereto, without first receiving an FDA-sanctioned investigational new drug application in accordance with 21 U.S.C. 355(i) and 21 C.F.R. Part 312.

(q) Each pharmacist or pharmacy compounding sterile preparations shall have the following resources:

(1) A primary engineering control that is currently certified by an inspector certified by the controlled environmental testing association to ensure aseptic conditions within the working area and that has the required documentation. The certification shall be deemed current if the certification occurred within the previous six months or on the date the device was last moved to another location, whichever is more recent. The required documentation shall include the following:

(A) Inspection certificates for the past five years or since the date of installation, whichever is more recent;

(B) records of all filter maintenance for the past five years or since the date of installation, whichever is more recent;

(C) records of all HEPA filter maintenance for the past five years or since the date of installation, whichever is more recent; and

(D) records of all disinfecting and cleaning for the past year or since the date of installation, whichever is more recent;

(2) a sink with hot and cold running water;

(3) a refrigerator capable of maintaining a temperature of 2° to 8°C (36° to 46°F) and, if needed, a freezer capable of maintaining a temperature of -25° to -10°C (-13° to 14°F). The temperature shall be monitored and recorded each business day. Each pharmacy with an electronic system that alerts the pharmacist to noncompliant temperatures shall be exempt from daily recording;

(4) the reference materials required by K.A.R. 68-2-12a and a current copy of a reference text on intravenous incompatibilities and stabilities. If an electronic library is provided, a workstation shall be readily available for use by pharmacy personnel, students, interns, and board personnel;

(5) a policy and procedure manual, with a documented review at least every two years by the pharmacist-in-charge or designee, which shall include the following subjects:

(A) Sanitation;

(B) storage;

(C) dispensing;

(D) labeling;

(E) destruction and return of controlled substances;

(F) recordkeeping;

(G) recall procedures;

(H) responsibilities and duties of supportive personnel;

(I) aseptic compounding techniques; and

(J) ongoing evaluation of all staff compounding sterile preparations; and

(6) supplies necessary for compounding sterile preparations.

(r) Each pharmacist-in-charge shall maintain a uniform formulation record for each sterile preparation, documenting the following:

(1) The quantities, strength, and dosage form of all components of the sterile preparation;

(2) the equipment used to compound the sterile preparation and the mixing instructions;

(3) the container used in dispensing;

(4) the storage requirements;

(5) the beyond-use date to be assigned;

(6) quality control procedures, which may include monitoring the following, if applicable:

(A) Adequacy of mixing to ensure uniformity and homogeneity; and

(B) the clarity, completeness, or pH of solutions;

(7) the sterilization methods;

(8) the source of the formulation; and

(9) the name of the pharmacist who verified the accuracy of the formulation record and the date of verification.

(s) Each pharmacist-in-charge shall maintain on the original order or on a separate, uniform record a compounding record for each sterile preparation, documenting the following:

(1) The name and strength of the sterile preparation;

(2) the formulation record reference for the sterile preparation;

(3) the name of the manufacturer or repackager and, if applicable, the lot number and the expiration date of each component;

(4) the total number of dosage units or total quantity compounded;

(5) the name of the person or persons who compounded the sterile preparation;

(6) the name of the pharmacist, or the pharmacy student or intern working under the direct supervision and control of the pharmacist, who verified the accuracy of the sterile preparation;

(7) the date of compounding;

(8) the assigned internal identification number, if applicable;

(9) the prescription number, if assigned;

(10) the results of quality control procedures;

(11) the results of the sterility testing and, if applicable, pyrogen testing for the batch; and

(12) the assigned beyond-use-date. In the absence of valid scientific stability information that is applicable to a component or the sterile preparation, the beyond-use date shall be established in accordance with the following criteria:

(A) For nonaqueous and solid formulations, one of the following:

(i) If the manufactured drug product is the source of the active ingredient, six months from the date of compounding or the time remaining until the manufactured drug product's expiration date, whichever is earlier; or

(ii) if the substance listed in an official compendium is the source of an active ingredient, six months from the date of compounding or the time remaining until the expiration date of any component of the formulation, whichever is earlier;

(B) for formulations containing water and made from ingredients in solid form, not more than 14 days when stored under refrigeration; and

(C) for all other formulations, not longer than the intended duration of therapy or 30 days, whichever is earlier.

(t) The compounding record and corresponding formulation record specified in subsections (s) and (r), respectively, shall be retained at the pharmacy for at least five years and shall be made readily available to the pharmacist-in-charge, the board, and the board's designee.

(u) Medical care facility pharmacies shall generate a compounding record and a corresponding formulation record only for batch compounding or for any sterile preparation with a beyond-use date of more than seven days.

(v) Except when compounding in any CAI, each person involved in compounding a sterile preparation shall follow personal garbing and washing procedures that include the following minimum requirements:

(1) Preparing for garbing by removing any outer garments, cosmetics, jewelry, and

artificial nails;

(2) performing the following procedures, in the order listed:

(A) Donning dedicated shoes or shoe covers;

(B) donning head and facial hair covers;

(C) either washing the hands with soap for at least 20 seconds or using an antiseptic hand scrub in accordance with the manufacturer's instructions; and

(D) donning a nonshedding gown; and

(3) entering the work area and immediately performing an antiseptic hand-cleaning procedure using an alcohol-based surgical hand scrub and successively donning sterile, powder-free gloves. Sterile gloves shall be disinfected after touching any nonsterile area.

(w) All sterile preparations shall be stored and delivered in a manner that is designed to maintain parenteral product stability and sterility.

(x) All sterile preparations, except for sterile preparations for immediate use, shall be compounded under aseptic conditions as follows:

(1) Each low-risk sterile preparation labeled with a beyond-use date of 12 hours or longer shall be compounded in an ISO class five environment using techniques that ensure sterility. Each low-risk sterile preparation labeled with a beyond-use date of less than 12 hours shall, at a minimum, be made in a segregated compounding area.

(2) Each medium-risk sterile preparation shall be compounded in an ISO class five environment using techniques that ensure sterility.

(3) Each high-risk sterile preparation made with nonsterile components shall be sterilized

before being administered to a patient and shall have a certificate of analysis indicating that all nonsterile components meet the standards of the "United States pharmacopeia" and the FDA for identity, purity, and endotoxin levels as verified by a pharmacist.

(y) Each pharmacist engaged in the dispensing of sterile preparations shall meet all labeling requirements under state and federal law. In addition, the label of each sterile preparation shall contain the following information:

(1) The name and quantity of each component;

(2) the beyond-use date;

(3) the prescribed flow rate;

(4) the name or initials of each person who compounded the sterile preparation; and

(5) any special storage instructions.

(z)(1) The pharmacist-in-charge and all personnel involved in compounding sterile preparations shall have practical or academic training in sterile compounding, clean room technology, laminar flow technology, and quality assurance techniques. The training shall include the following:

(A) At least one successful media fill test; and

(B) a successful glove fingertip test.

(2) The pharmacist-in-charge shall ensure that all supportive personnel are trained and successfully demonstrate the following before performing any delegated sterile admixture services:

(A) Comprehensive knowledge of the pharmacy's standard operating procedures with

regard to sterile admixture services, as specified in the policy and procedure manual;

(B) familiarity with the compounding techniques; and

(C) aseptic technique, which shall be proven by means of a media fill test and a glove fingertip test.

(3) The pharmacist-in-charge shall be responsible for testing the aseptic technique of all personnel involved in compounding sterile preparations annually by means of a media fill test. All personnel involved in compounding high-risk sterile preparations shall undergo this testing twice each year. Each individual who fails to demonstrate acceptable aseptic technique shall be prohibited from compounding sterile preparations until the individual demonstrates acceptable technique by means of a media fill test.

(aa) The pharmacist-in-charge shall document all training and test results for each person before that person begins compounding sterile preparations. This documentation shall be maintained by the pharmacy for at least five years and shall be made available to the board upon request.

(bb) The pharmacist-in-charge shall be responsible maintaining records documenting the frequency of cleaning and disinfection of all compounding areas, according to the following minimum requirements:

(1) Each ISO class five environment shall be cleaned and disinfected as follows:

(A) At the beginning of each shift;

(B) every 30 minutes during continuous periods of compounding individual sterile preparations;

(C) before each batch; and

(D) after a spill or known contamination.

(2) All counters, work surfaces, and floors shall be cleaned and disinfected daily.

(3) All walls, ceilings, and storage shelves shall be cleaned and disinfected monthly.

(cc) The pharmacist-in-charge shall be responsible for maintaining records documenting the monitoring of the air pressure and air flow and shall initiate immediate corrective action if indicated. The air pressure of the antearea shall be maintained at five pascals, and the air flow shall be maintained at 0.2 meters per second. The air pressure and air flow values shall be checked and recorded at least once daily.

(dd) The pharmacist-in-charge shall be responsible for maintaining records documenting the monitoring of the cleanliness and sterility of the sterile compounding environment. Environmental sampling shall be performed in each new facility before any sterile preparation in that facility is provided to a patient and, at a minimum, every six months thereafter. The environmental sampling shall include the primary engineering control, antearea and buffer area, and equipment and shall be performed following any repair or service performed at the facility and in response to any identified problem or concern.

Environmental sampling shall consist of the following, at a minimum:

(1) Environmental nonviable particle counts;

(2) environmental viable airborne particle testing by volumetric collection;

(3) environmental viable surface sampling; and

(4) certification of operational efficiency of the primary engineering control by an

independent contractor according to the international organization of standardization classification of particulate matter in room air, at least once every six months.

(ee) The environmental sampling records specified in subsection (dd) shall be retained at the pharmacy for at least five years and shall be made readily available to the pharmacist-in-charge, the board, and the board's designee.

(ff) If a microbial growth above acceptable levels is detected in an ISO class five environment, ISO class seven environment, or ISO class eight environment, an immediate reevaluation of the adequacy of compounding practice, cleaning procedures, operational procedures, and air filtration efficiency with the aseptic compounding location shall be conducted and documented. Each investigation into the source of the contamination shall include air sources, personnel garbing, and all filters, at a minimum. The ISO class five environment, ISO class seven environment, or ISO class eight environment shall be cleaned three times and environmental sampling shall be performed and reevaluated. Sterile preparations may be compounded and labeled with a beyond-use date according to subsection (gg) until microbial growth has decreased to acceptable levels.

(1) An ISO class five environment shall have acceptable levels of microbial growth if both of the following conditions are met:

(A) An airborne sample demonstrates no more than one colony-forming unit per cubic meter of air.

(B) A surface sample demonstrates no more than three colony-forming units per contact plate.

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(2) An ISO class seven environment shall have acceptable levels of microbial growth if both of the following conditions are met:

(A) An airborne sample demonstrates no more than 10 colony-forming units per cubic meter of air.

(B) A surface sample demonstrates no more than five colony-forming units per contact plate.

(3) An ISO class eight environment shall have acceptable levels of microbial growth if both of the following conditions are met:

(A) An airborne sample demonstrates no more than 100 colony-forming units per cubic meter of air.

(B) A surface sample demonstrates no more than 100 colony-forming units per contact plate.

(gg) Unless sterility has been confirmed by testing, each high-risk sterile preparation shall be administered according to the following:

(1) Within 24 hours of compounding if stored at room temperature;

(2) within three days of compounding if stored under refrigeration; or

(3) within 45 days of compounding if stored frozen at -20°C (-4°F) or colder.

(Authorized by K.S.A. 65-1630 and K.S.A. 2017 Supp. 65-1637e; implementing K.S.A. 2017 Supp. 65-1626a, K.S.A. 65-1634, K.S.A. 2017 Supp. 65-1637c, and K.S.A. 2017 Supp. 65-1642; effective P-_____.)

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